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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,102	09/10/2003	Mitchell J. Bellucci	BELLU-002XX	6872

207 7590 03/23/2007

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EXAMINER	
TOWA, RENE T	
ART UNIT	**PAPER NUMBER**
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,102	BELLUCCI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed December 27, 2006. Claims 1-25 are pending. Claims 1, 10, 15, 20-21 are amended. New claims 22-25 have been added. No claim has been canceled.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claim 15, at line 14, the step of "separating the sampling reservoir from the sampling device" before "analyzing the collected fluid" is not supported by the specification. Moreover, Applicant has failed to disclose where in the specification one would find support this newly introduced method step. Applicant has further failed to state that no matter is being introduced.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1, at line 8, the limitations "the sampling needle" render the claim indefinite; for example, from the alternative language used in line 6, it is unclear whether or not the device includes a single or a plurality of sampling needles.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 3, 11-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg (US Patent No. 5,690,646) in view of Aceti et al. (US Patent No. 6,540,675).

Gruenberg discloses a housing with a cavity adapted to receive an umbilical cord such that the cavity immobilizes the cord relative to the housing; and

at least one sampling needle enclosed within the housing and that is positioned for insertion into the umbilical cord within the cavity, the sampling needle being operatively connected to a removable cassette containing a sampling reservoir.

With regard to claim 1, Gruenberg discloses a housing, as described above, that teaches all the limitations of the claim except Gruenberg does not explicitly teach a plurality of needles and a reservoir.

However, Aceti et al. discloses a device comprising comprising at least one sampling needle 53 operatively connected to a removable cassette containing a

sampling reservoir 50 (see fig. 1; column 2/lines 26-38; column 3/lines 5-10; column 12/lines 30-36);

wherein the sampling device further includes a sensor (see column 9/lines 62-64; column 10/lines 9-16, 42-45 & 56-59);

wherein the sampling device further comprises a meter (see column 11/lines 26-37 & 56-60).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg with a removable cassette similar to that of Aceti et al. so that the portions of the device that contact biological fluid can be replaced by substituting the cassettes (see Aceti et al., column 12/lines 30-36).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg with a plurality of needles similar to that of Aceti et al. since such a modification would serve the same purpose of collecting blood from the umbilical cord (see Gruenberg, column 4/lines 3-8 & 11-15).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg with a sensor similar to that of Aceti et al. in order to measure physiological parameters of the body fluid.

Even moreover yet, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of

Gruenberg with a meter similar to that of Aceti et al. in order to display the measured physiological parameter.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) further in view of Knippscheer et al. (US Patent No. 5,114,672).

Gruenberg as modified by Aceti et al. discloses a system, as described above, that teaches all the limitations of the claims except Gruenberg as modified by Aceti et al. do not teach a roller.

However, Knippscheer et al. disclose a system comprising a roller 70 (see fig. 4).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al. with a roller similar to that of Knippscheer et al. in order to mix the blood inside the umbilical cord with an anticoagulant (see Knippscheer et al., column 4/lines 4-9, 43-49 & 52-57).

10. Claims 4-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) further in view of Lauks et al. (US Patent No. 5,779,650).

In regards to claim 4, Aceti et al. disclose(s) an umbilical cord sampling device further comprising a system including a removable cassette column 3/lines 5-10; column 12/lines 30-36).

In regards to claim 5, Aceti et al. disclose(s) an umbilical cord sampling system further comprising an analyzer (see column 11/lines 26-37 & 56-60).

In regards to claim 9, Aceti et al. disclose(s) an umbilical cord sampling system wherein the analyzer is in operative communication with a computer (see column 11/lines 26-37 & 56-60).

Gruenberg as modified by Aceti et al. disclose a system, as described above, that teaches all the limitations of the claim except Gruenberg as modified by Aceti et al. do not disclose a docking unit.

However, Lauks et al. disclose a system comprising a docking unit 120 that mates with a removable cassette 24 (see fig. 1; column 5/lines 53-64).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg as modified by Aceti et al. with a docking unit similar to that of Lauks et al. in order to stably secure the reservoir chamber to the device (see Lauks et al., column 6/lines 4-6).

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) further in view of Lauks et al. ('650) even further in view of Lauks et al. (US Patent No. 5,096,669).

Gruenberg as modified by Aceti et al. and Lauks et al. ('650) disclose a system, as described above, that teaches all the limitations of the claim except Gruenberg as modified by Aceti et al. and Lauks et al. ('650) do not teach a printer.

However, Lauks et al. ('669) disclose a system comprising a printer (see fig. 1; column 4/lines 21-25).

Since Gruenberg as modified by Aceti et al. and Lauks et al. ('650) disclose a system comprising a visual display (see Aceti et al., column 11/lines 56-60), it would

have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al. and Lauks et al. ('650) with a printer similar to that of Lauks et al. ('669) since both will serve the same purpose of outputting the results of the analysis.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) further in view of Lauks et al. ('650) even further in view of Baker et al. (US Patent No. 4,654,127).

Gruenberg as modified by Aceti et al. and Lauks et al. ('650) disclose a system, as described above, that teaches all the limitations of the claim except Gruenberg as modified by Aceti et al. and Lauks et al. ('650) do not teach a printer.

However, Baker et al. disclose a system comprising a printer (see column 4/lines 60-68).

Since Gruenberg as modified by Aceti et al. and Lauks et al. ('650) disclose a system comprising a visual display (see Aceti et al., column 11/lines 56-60), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al. and Lauks et al. ('650) with a printer similar to that of Baker et al. since both will serve the same purpose of outputting the results of the analysis (see Baker et al., see column 4/lines 60-68).

13. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) further in view of Lauks et al. ('650) even further in view of Gauthier et al. (US Patent No. 6,017,318).

In regards to claim 7, Gruenberg as modified by Aceti et al. and Lauks et al. ('650) disclose a system, as described above, that teaches all the limitations of the claim except Gruenberg as modified by Aceti et al. and Lauks et al. ('650) do not teach a bar code reader.

However, Gauthier et al. disclose a system comprising a bar code reader (see column 24/lines 5-6).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al. and Lauks et al. ('650) with a bar code reader similar to that of Gauthier et al. in order to read the information indicative of the specific activity of the tests (see Gauthier et al., column 12/lines 39-42 & 45-49).

Moreover, in regard to claim 8, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al., Lauks et al. ('650), and Gauthier et al. with a magnetic card reader since such a modification would serve the same purpose of reading the information indicative of the specific activity of the tests (see Gauthier et al., column 12/lines 39-42 & 45-49).

14. Claims 10 &13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Aceti et al. ('675) in view of Hessel et al. (US Patent No. 5,520,699).

Gruenberg as modified by Aceti et al. disclose a system, as described above, that teaches all the limitations of the claims except Gruenberg as modified by Aceti et al. do not explicitly teach a pH sensor or a lens in the housing.

However, Hessel et al. discloses a system comprising a pH sensor and a thin wall 220 (see column 10/lines 44-48 & 59-67; column 11/lines 1-2).

Since Aceti et al. teach a sensor, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Gruenberg as modified by Aceti et al. with a pH sensor similar to that of Hessel since such a modification would serve the same purpose of measuring a physiological parameter.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg as modified by Aceti et al. with a thin wall similar to that of Hessel in order to make saturated oxygen measurements by directing infra-red light through the thin wall (see Hessel, column 10/line 64 to column 11/line 2). Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Gruenberg as modified by Aceti et al. and Hessel with a lens in place of the thin wall 220 since such a modification would serve the same purpose of directing the infra-red light so as to measure the saturated oxygen measurement.

15. Claims 15-16, 18-19 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg (US Patent No. 5,690,646) in view of Hessel et al. (US Patent No. 5,520,699).

Gruenberg disclose(s) a method, comprising the steps of:

providing an umbilical cord sampling device 10 having at least one sampling needle 28 positioned with the device housing such that the needle is operatively connected to at least one sampling reservoir (i.e. blood collection bag);

wherein the sampling device includes a housing with a cavity 12 that immobilizes the cord segment relative to the housing;

wherein the sampling reservoir is attached to a device with a connector 32 (see column 4/lines 3-8);

placing an umbilical cord segment in the umbilical cord sampling device 10 (see figs. 1-2);

penetrating a fluid-containing lumen of the umbilical cord segment with a sampling needle 28;

collecting the fluid through the sampling needle in a sampling reservoir;

moving a needle tip of the sampling needle into the cord segment (see figs. 1-3; column 2/lines 7-59).

Gruenberg discloses a method, as described above, that teaches all the limitations of the claim except Gruenberg does not teach a step of analyzing the collected fluid to determine values of physiological parameters.

However, Hessel et al. disclose a method comprising the step of analyzing a collected fluid with a probe to determine values of physiological parameters; wherein the method comprising measuring fluid with a sensor (probe); wherein the method comprises measuring blood gas value (i.e. saturated oxygen measurements); wherein

the method comprises measuring blood pH (see column 10/lines 56-66); wherein the method further includes separating the sampling reservoir 22 from the sampling device 10 and analyzing the separated body fluid (see column 4/lines 4-50).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a sensor similar to that of Hessel et al. in order to make measurement of the blood (see Hessel et al., column 10/lines 59-60).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gruenberg with a step separating and analyzing the fluid similar to that of Hessel et al. in order to automatically deliver adequate samples of uncontaminated cord blood suitable for current laboratory analysis to protected containers (see Hessel et al., column 2/lines 27-35).

16. Claims 17 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Hessel et al. ('699) further in view of Aceti et al. (US Patent No. 6,540,675).

Gruenberg as modified by Hessel et al. discloses a method, as described above, that teaches all the limitations of the claims except Gruenberg as modified by Hessel et al. does not disclose measuring a blood analyte or communicating values to a computer. However, Aceti et al. discloses a method comprising the steps of disclose measuring a blood analyte (i.e. glucose) and communicating values to a computer (see column 3/lines 13-14 & 21-25; column 9/lines 62-64; column 10/lines 9-16, 42-45 & 56-59; column 11/lines 26-37 & 56-60).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gruenberg as modified by Hessel et al. with a step of measuring a blood analyte similar to that of Aceti et al. in order to monitor the blood analyte level (i.e. whether or not is falls within the norm).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gruenberg as modified by Hessel et al. with a step of communicating the values to a computer similar to that of Aceti et al. in order to report the measured value (see Aceti et al., column 11/lines 15-25).

Response to Arguments

17. Applicant's arguments filed December 27, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

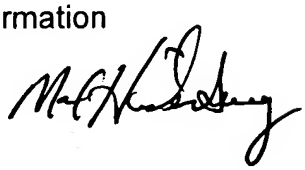
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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